Remarks

The decision of the Board of Patent Appeals and Interferences reversed all outstanding appealed rejections but entered a new ground of rejection under 35 U.S.C. 112, first paragraph on the ground that Claim 11 did not define the relevant peptide in structural terms. The newly amended claim requires that the relevant peptide contain one the sequences SPNC or SPPC and thus at a minimum includes mouse and human p53as. In view of the other peptide description, the inclusion of specific sequences now meets the Boards requirements for "structural features common to the members of the genus." Claim 11 is thus correspondingly narrowed. If a peptide does not contain either SPNC or SPPC, it is not a member of the "genus" as now defined. One skilled, in the art can thus now easily "visualize or recognize the identity of the members of the genus."

In view of the amendment and above remarks, the new ground of rejection, therefore, clearly no longer applies and should be withdrawn.

While the Board entered no other ground of rejection, it did raise another "issue" which is preliminarily addressed here. The question was raised as to whether the Han et al. reference reasonably suggests to one of ordinary skill a purified peptide reproducing the distinctive C-terminal 25-amino acid sequence to be used for inducing the desired specific antibody."

The answer is that **Han et al. makes no such suggestion**. The suggestion by the Board to examine the question of obviousness based upon Han et al. is merely that, a suggestion to examine. The Board recognizes that upon examination, obviousness may not be supportable. The questions raised by the Board are only raised based upon hindsight. There are therefore a

number of issues that must be addressed. First, does the Han et al. reference itself permit the formulation of the questions without hindsight construction? Secondly, can the answers be made based upon the Han et al. reference without hindsight reconstruction? Thirdly, even if answers could be obtained from Han et al. to questions not based upon hindsight, would the answers support an obviousness rejection? Failure to answer any one of these issues in the affirmative would be enough to eliminate Han et al. as a reference that renders the present claim obvious. In fact none of these issues can be answered in the affirmative.

The Board says that Han et al. teaches that the "sequence of the 3' ends of the alternatively spliced p53 nucleic acids are identical to those of Arai" (pp. 1980-1981). The meaning of Han et al. in this regard and the assumptions made by the Board in this regard are not at all clear. The passage in Han et al. refers to molecular weight and number of base pairs. It is not clear that all base pairs are the same and it is unclear whether they were sequenced. Further, the data of Han et al. in the passage shows an identity of molecular weight for 613 and 517 bp bands (not protein or peptide). This disclosure clearly does not suggest a peptide having a unique epitope as currently claimed.

The Board then points out that Han et al. says on page 1981 that a p53 protein encoded by alternatively spliced RNA would differ from the regular p53 protein by 25 amino acids at the C-terminus, that the termini are distinct and that the difference **"could"** lead to significant biochemical and biological changes. The Boards quotation of Han et al. is not quite accurate. Han et al. actually says that the "AS-p53 RNA species are **'predicted'** to result in premature termination of p53 protein, making it 9 amino acids shorter and differing in 25 amino acids at the

C-terminus. In fact Han et al could only **"predict". There is no disclosure in Han et al of any protein and certainly not any peptide.** Any reference by Han et al to p53as protein is **"prediction".** Even with the unproven "prediction" Han et al. could only speculate that there "**could**" be biological significance. There is certainly no disclosure or suggestion of what that significance might be. **There is definitely no suggestion of the presently claimed peptide.**

The question raised by the Board as to whether a peptide in the terminal sequence would raise a specific antibody, is a hindsight question. Why was it asked? Certainly nothing in Han et al. disclosure suggests that it should be asked. One need go no farther to show unobviousness over Han et al. However, in addition, even if the question could be appropriately asked, there is no reason to look at Han et al. to answer it. Han does not suggest anything concerning unique antibodies even for his speculated p53as protein, let alone any specific peptide from that protein. **One cannot go to Han et al. to find any suggestion at all that a unique antibody could be raised to the claimed sequence.**

Han et al. clearly cannot be properly used as a basis for a rejection under 35 U.S.C. 103.

In view of the foregoing amendments and remarks, the new ground of rejection should be withdrawn and the claim should be allowed.

Respectfully submitted,

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Version with markings to show changes made

11. (amended) A purified peptide designated p53as peptide which peptide is present in p53as protein of a mammal and is identical to the unique carboxy terminal region of p53as which distinguishes p53as protein from p53 protein, said peptide containing a unique epitope which is not present in p53 said peptide containing a peptide sequence selected from the group consisting of SPNC and SPPC.